

### **REMARKS**

Applicant hereby replies to the Examiner's Notice of Non-Compliant Amendment mailed August 8, 2007, and in reply to the Office Action dated March 1, 2007, of which this REPLACEMENT Reply is filed within the shortened one month statutory period for reply. **This Reply should REPLACE the previous Reply filed on June 1, 2007.**

Claims 1-22 and 25 were pending in the application and the Examiner rejects claims 1-22 and 25. Reconsideration of the pending claims is requested. The amendments are adequately supported in the originally-filed specification, drawings and claims. No new matter is added in this Reply.

Applicant amends claims 11 and 17 and support for the amendments are found at, for example, paragraphs 0007, 0027 ("wire 12 is comprised of a thin metal such as, for example, stainless steel, titanium and/or titanium alloy, so it may be easily cut to almost any desired length,"), 0028 ("This configuration also allows cap 20 to slide along wire 12 without the need for spinning cap 20 which is important because time is of the essence in a medical procedure and spinning the cap down a sufficiently long length of wire would be very time-consuming,"), 0028 ("such that cap 20 is restricted from backwards translation after cap 20 is inserted over wire 12") and 0033 ("Cap 20 is then translated distally along wire 12 until cap 20 contacts the bone or other desired pathology.").

Applicant amends claims 9 and 13, as suggested by the Examiner, to correct minor grammatical issues.

The Examiner rejects claims 6, 12, and 18 under 35 USC § 112 because of antecedent basis and definiteness issues. Applicant amends claims 6, 12, and 18 to correct the concerns, so the rejection of claims 6, 12, and 18 are now moot.

The Examiner rejects claims 1-6, 8, 11-15, 17, 19-21 and 25 under 35 USC § 102(a) as being anticipated by HEHL, WO 00/67652 A2 ("Hehl"). Applicant respectfully traverses this rejection.

As between the outer surface of the Hehl shaft and the inner surface of the Hehl cap, the Hehl device only discloses or suggests ONE sawtooth configuration. All of the Hehl figures consistently disclose one sawtooth surface and a peg or dowel interfacing with the sawtooth surface to restrict translation. In other words, Hehl does not include any "inverse" sawtooth configuration to mate with the sawtooth configuration. Importantly, the use of a peg or dowel,

instead of an inverse sawtooth configuration is significant in that such peg or dowel does not provide as much frictional force between the two surfaces in order to sufficiently restrict translation. Moreover, if the single peg or opposing pegs break or bend, then a significant reduction in friction results. In contrast, an inverse sawtooth includes many points of contact between the two surfaces. As such, Hehl does not disclose or suggest at least “wherein said first interface includes a sawtooth configuration; and, . . . a second interface component including an inverse sawtooth configuration,” as recited by independent claim 1.

Applicant also asserts that Hehl does not disclose or suggest that bolt 9 may be easily bent by the surgeon without the use of heavy tools, or that bolt 9 may be easily cut using a simple wire cutter. To the contrary, the Hehl device explicitly states that the shaft is a “bolt” wherein a bolt includes a set length, a firm composition and a large diameter. While the excess portion of the bolt may be removed, the rigid nature of the Hehl rod would require a hacksaw or other cumbersome tool which would increase the time and skills needed for the procedure, along with decreasing the sterility and stability of the process (e.g., damaging vibrations, metal shavings distributed from the sawing process). The Hehl device also requires different sized bolts and bushings. As such, the Hehl device would literally destroy the benefits and functionality of the presently claimed invention. As set forth in the Background section of the present application, one purpose of the present invention is to avoid the need for numerous cap and bolt sizes, along with avoiding the need for managing large sets of caps and rods that need to constantly be replaced. As such, Hehl does not disclose or suggest at least “wherein said flexible wire is at least one of bendable without the use of tools and is able to be cut with a wire cutter,” as recited by independent claims 11, 14 and 17.

Applicant asserts that dependent claims 2-6, 8, 12, 13, 15, 19-21 and 25 variously depend from independent claims 1, 11, 14 and 17, so claims 2-6, 8, 12, 13, 15, 19-21 and 25 are differentiated from the cited reference for the same reasons as set forth above, in addition to their own respective features.

The Examiner next rejects claims 17, 20 and 21 under 35 USC § 102(b) as being anticipated by Fletcher, U.S. Patent No. 6,050,998 (“Fletcher”). Applicant respectfully traverses this rejection.

The Examiner asserts that the Fletcher barbs 28 terminate within the first surface in Fletcher Figures 6D and 9. Applicants assert that the Fletcher barbs do not cut into the first surface which may significantly reduce the binding strength of the Fletcher device.

Moreover, the Fletcher device includes a loop device which must enter and exit each object (or bone portion) being fixated while also traveling through an extended canal in each object. As such, the Fletcher device requires an entrance hole, exit hole and an extended canal in each bone portion, thereby substantially increasing, for example, the risk of infection, additional damage to the bone, loss of bone integrity, additional time in surgery and additional healing time. Moreover, the “cap” portion of the Fletcher device is connected to both ends of the wire, thereby increasing the size of the cap portion, and increasing the number of components adhering to the cap portion, thereby creating additional problems for burying the cap portion within the bone. As such, a larger hole is needed to bury the cap portion and the other end of the wire exits from the burying hole and outside of the bone, thereby again increasing risk of infection additional damage to the bone, loss of bone integrity, additional time in surgery and additional healing time. In contrast, the presently claimed invention does not require an additional exit hole, a canal, a loop exiting the bone, nor additional components on the cap.

Accordingly, Fletcher does not disclose or suggest at least “inserting said head component having cutting threads into, and terminating within, said first surface, wherein said head component cuts into said first surface with said cutting threads” as recited in independent claim 17.

Applicant asserts that dependent claims 20 and 21 depend from independent claim 17, so claims 20 and 21 are differentiated from the cited reference for the same reasons as set forth above, in addition to their own respective features.

The Examiner next rejects claims 17-20 under 35 USC § 102(b) as being anticipated by Goble, et al., U.S. Patent No. 5,702,397 (“Goble”). Applicant respectfully traverses this rejection.

Applicant asserts that Goble is limited to forming a tunnel, inserting a bone anchor, inserting a suture through the bone anchor and attaching the suture to the ligament graft to allow the graft to be pulled through the bone anchor and then clamped to the suture. The Goble device allows the suture and graft to travel through the bone anchor and does not apply pressure between two portions of a bone. Moreover, the suture is not affixed to the anchor prior to

inserting the anchor into the bone and the pressure applied to the suture is due to the pulling by the ligament graft, and not by any type of head component or cap. Additionally, the Goble anchor must be rotated to secure its cap into its anchor portion, such that the cap and anchor become one piece. Such rotation may disrupt or injure other portions of the body, along with spiraling fluid and unwanted materials through the canal. In contrast, the presently claimed invention includes a cap which translates along the flexible wire. Moreover, the cap and anchor portion are in the same location within the same portion of the fractured bone. **In contrast, the cap of the presently claimed invention is only translated over the portion of the wire in the second surface (while the head component is in the first surface)**. Accordingly, Goble does not disclose or suggest at least “translating a cap over an end portion of said flexible wire within said second surface, wherein said cap and head component are separated by a distance,” nor a system which “apply pressure between said first bone portion and said second bone portion,” as recited by independent claim 17.

Applicant asserts that dependent claims 20 and 21 depend from independent claim 17, so claims 20 and 21 are differentiated from the cited reference for the same reasons as set forth above, in addition to their own respective features.

The Examiner rejects claims 1-22 and 25 under 35 USC § 103(a) as being unpatentable over Dakin, U.S. Patent No. 6,368,326 (“Dakin”) in view of Cachia, U.S. Patent No. 5,893,850 (“Cachia”). Applicant respectfully traverses this rejection.

The Dakin device is limited to a bone fixation device which includes a cord lock having a second threaded member received into the bore of one of a plurality of fasteners. The presently claimed invention does not include rotational threads for locking in the flexible wire into an anchor, and instead, includes a cap which translates over the flexible wire. The benefits of a cap that translates over the wire, without rotation, are significant. For example, rotation is more likely to disrupt the fixation and introduce (by spiral action) infection and other undesirable products into the bone. Dakin cord 22 does not include any type of inverse sawtooth interface on its surface; instead, Dakin requires another component, namely a lock screw 28 to provide an interface. The Cachia pin is a set length, so the hospital would be required to keep many different pin lengths available. In contrast, the presently claimed invention uses a flexible wire that is cut to the desired length, thereby reducing the need for storing multiple lengths.

Importantly, no motivation exists to combine Dakin with Cachia because the Dakin lock screw would not be needed. Moreover, it would be very difficult, if not impossible, to rotate the Dakin lock screw over a cord with a sawtooth outer surface. Furthermore, the internal surface of the Dakin cap 24 includes a spiral groove to receive the Dakin lock 28. Again, such a spiral groove would not provide a sufficient inverse interface with the inverse sawtooth on the outside of the cord. Accordingly, neither Dakin, Cachia, nor any combination thereof, disclose or suggest at least “with certain of said inverse sawteeth sliding over certain of said sawteeth,” as similarly recited in independent claim 1 and 14.

Moreover, Dakin requires that a component of its cap, namely the lock screw 28 portion of the cap, be rotated in order to apply the device to a bone fracture. In contrast, the presently claimed invention includes an entire cap which is not rotated. As set forth above, significant medical benefits exist from avoiding rotation of any portion of the cap. Moreover, the Dakin cap requires the Dakin lock 28 to restrict the reverse translational movement of cord 22. In contrast, the presently claimed invention uses the inside surface of the cap to restrict the reverse translational movement. Accordingly, neither Dakin, Cachia, nor any combination thereof, disclose or suggest at least “a cap which mates, without rotation of said cap, with said second end of said flexible wire by translating along said flexible wire while an inside surface of said cap restricts reverse translational movement,” as similarly recited by independent claims 11 and 17.

Applicants also assert that no motivation to combine Dakin and Cachia exists because the combination would exponentially increase the significant limitations, sterility and mechanical problems with a combined device. The combination would still include the extra locking device which must be rotated, expanding lever arms, a single set length pin and an anchor. More specifically, the Cachia patent discloses a bone fixation device for connecting bones or bone fragments. However, the Cachia disclosure is limited to a single pin with (i) expanding lever arms which are compressed during insertion through the entire bone, then the lever arms expand after exiting out of the other side of the bone; and, (ii) an anchor which rotates around the threads on the other end of the pin.

The Cachia pin is a set length, so the hospital would be required to keep many different pin lengths available. In contrast, the presently claimed invention uses a flexible wire that is cut to the desired length, thereby reducing the need for storing multiple lengths. Moreover, the

presently claimed invention does not include rotational threads for rotating an anchor, and instead, includes a cap which translates over the flexible wire.

Furthermore, the Cachia lever arms are mechanical which include the obvious mechanical failures and the extension through the entire surface of the bone includes obvious discomfort issues for the patient, susceptibility to being hit or moved, longer surgery times and infection issues. In contrast, the presently claimed invention does not extend through the entire surface of the bone which minimizes or eliminates many of the disadvantages of the Cachia device. Accordingly, Cachia does not disclose or suggest at least a "flexible wire", "said head component inserted into, and terminating within, one of said objects," nor "said cap is configured to translate along said wire," as similarly recited by independent claims 1, 11 and 17.

Applicant asserts that dependent claims 2-10, 12-13, 15-16, 18-22 and 25 variously depend from independent claims 1, 11, 14 and 17, so claims 2-10, 12-13, 15-16, 18-22 and 25 are differentiated from the cited reference for the same reasons as set forth above, in addition to their own respective features.

Applicant respectfully submits that the pending claims are in condition for allowance. The Commissioner is hereby authorized to charge any fees, which may be required, or credit any overpayment, to Deposit Account No. **19-2814**. Applicant invites the Examiner to telephone the undersigned, if the Examiner has any questions regarding this Reply or the present application in general.

Respectfully submitted,

Dated: August 14, 2007

By: 

Howard I. Sobelman  
Reg. No. 39,038

**SNELL & WILMER L.L.P.**  
400 E. Van Buren  
One Arizona Center  
Phoenix, Arizona 85004  
Phone: 602-382-6228  
Fax: 602-382-6070  
Email: [hsobelman@swlaw.com](mailto:hsobelman@swlaw.com)